guidlines and pricing and reimbursement legislation. **RESULTS:** The survey analyses pharmacoeconomic guideline of the National Council on prices and reimbursement for inclusion of new INN in the positive drug list in Bulgaria. Requirements for efficacy, safety, benefits, adverse events, comparator, standard treatment, drug utilization, budget impact, patient population during the premarketing and postmarketing period are change in order to provide data with higher quality for the decision making process . From April 2013 to July 2015. Over that period more than 36 new INNs were accepted for reimbursement in Bulgaria. A guideline with an HTA approach for assessment of submitted dossiers was introduced in April 2015 The experience in that field of other MSs is summarized and compared. **CONCLUSIONS:** The study evaluates how NCPR develops recommendations and reimbursement decisions on the basis of one step procedure which shortens the pricing and reimbursement process in comparison with other EU MSs. No published criteria how to evaluate the submitted pharmacoeconomic information by the expert of the NCPR are publicly available and HTA appraisal may be subjectively biased.

PHP206

HOW DOES THE ADDITIONAL BENEFIT EXTENT OF ORPHAN DRUGS IMPACT PRICE NEGOTIATIONS IN THE GERMAN OUTPATIENT SECTOR?

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OBJECTIVES: For orphan drugs an additional benefit is granted by market authorization of the EMA. In case orphan drugs exceed an annually turnover of 1m Euro (based on ex. pharmacy prices) in the outpatient sector recently authorized orphan drugs have to undergo an assessment of the additional benefit extent by the Federal Joint Committee. Based on the results pharmaceutical manufacturer and the head association of the statutory health insurance negotiate rebates. The objective of this analysis is to assess whether the additional benefit extent of orphan drugs does impact the rebate size of the price negotiations. **METHODS:** In a first step orphan drugs affected by an assessment of additional benefit extent were analyzed within the German market. The dependency between additional benefit extent and rebate size of negotiations is assessed by correlation analysis. This analysis is based on relevant public available data of the Federal Joint Committee as well as price related rebate information related to the AMNOG process for orphan drugs. **RESULTS:** By May 2015, 10 of currently 77 in Germany registered orphan drugs passed the AMNOG legislation comprising the assessment of additional benefit extent as well as associated price negotiations. Thereby rebates sizes ranging from 9% up to almost 44%. The analysis of the additional benefit extent and the rebate size showed no correlation between the two parameters. **CONCLUSIONS:** The hypothesis of an inversely proportional dependence between additional benefit extent and rebate size was refuted by this analysis. Following this a larger benefit extent tends not to impact price negotiations in terms of a rebate reduction. However, the small sample size tends to limit power of the analysis.

PHP207

QUANTITATIVE ASSESSMENT OF CANADIAN PROVINCIAL PUBLIC FUNDING DECISIONS FOR ONCOLOGY DRUGS FOLLOWING PCODR ECONOMIC EVALUATIONS FOR 2013 AND 2014

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OBJECTIVES: Canadian provinces are encouraged to follow HTA recommendations conducted under pCODR for cancer drugs, but have ultimate authority over the final reimbursement decision on public drug plans. In order to understand the impact of HTA assessments on market access of oncology drugs and highlight variations across the individual jurisdictions we conducted a quantitative analysis of all pCODR's oncology assessments completed in 2013-14 and consequent funding decisions implemented by the provinces. **METHODS:** Data, obtained from the pCODR database for all 27 assessments completed in 2013 and 2014, were used to estimate median time to pCODR final decision and the time to first funding approval in one of the nine provinces excluding Quebec. We also examined the probability of obtaining public drug plan approval in Canada based on the pCODR recommendation. **RESULTS:** On average, 74% of the assessments resulted in a favourable decision by the provinces, compared to 88% with a favourable pCODR recommendation. However, positive provincial funding decisions varied considerably (88% in Ontario, Manitoba, and Saskatchewan, to 32% in Prince Edward Island). At the time of analysis 16% of drugs were still awaiting provincial funding assessment, while 10% received no funding primarily after a "no funding" pCODR recommendation. The median time between marketing approval and a final pCODR decision was 200 days; the median time between that final decision and receiving the first funding approval was 115 days. Provincial funding decisions under pCPA joint negotiations took longer (median of 118 days) compared to those negotiated separately (80 days). **CONCLUSIONS:** It takes nearly four months for provinces to begin funding new drugs after a final HTA decision is issued, with funding decisions in other jurisdictions lagging further behind. Multiple levels of pricing and reimbursement regulations and a highly fragmented pharmaceutical market are likely impacting market access for new drugs in Canada.

PHP208

VALUE JUDGMENT OF HEALTH INTERVENTIONS FROM DIFFERENT PERSPECTIVES: ARGUMENTS AND CRITERIA

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OBJECTIVES: The healthcare sector is evolving while life expectancy is increasing. These trends put greater pressure on resources, prompt reforms, and demand transparent arguments and criteria to assess the overall value of health interventions. Besides (cost) effectiveness, many criteria play a role when determining the value of interventions. There is no consensus on the core arguments. This study aimed at retrieving the most widely recognized arguments used in making decisions about patient treatments and prioritizing interventions, and to compile a smaller set that would seem most relevant to different stakeholders. **METHODS:** A landscape review was performed in Medline and EMBASE. Initial search retrieved over 2000 articles. After a selection based on reference to healthcare, policy issues, or social justice, 64 papers were included. Data were extracted and a full table was made, including all arguments found; next, identical or largely overlapping criteria were excluded and a reduced set was compiled. **RESULTS:** The final set included 26 arguments, categorized by type (clinical, social justice, ethical, and policy). Examples of arguments included in the final set are: Longevity, need, dignity and public health value. For each argument, relevance to stakeholders was scored on three levels (not, partly, and completely relevant). **CONCLUSIONS:** Many arguments play a role in making decisions about patient treatments, but not all are relevant to all interventions. Moreover, they may interact with each other. Therefore, systematic and analytical approaches such as multi-criteria decision analysis may be not suitable. As such, a viable way to deal with interacting and possibly conflicting arguments might be to arrange public discussions that would evoke different stakeholders' perspectives.

PHP209

FDA BREAKTHROUGH MEDICINES; HAVE THEY CAUSED BREAKTHROUGH HEADACHES FOR HTA AGENCIES?

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OBJECTIVES: FDA breakthrough therapy designation was created in 2012 to expedite the registration of new health care technologies for use by patients with serious or life-threatening diseases/conditions. Breakthrough therapies are eligible for other FDA regulatory programs such as fast track designation, accelerated approval and priority review. We sought to determine whether other regulators and HTA agencies/payers also sought to expedite access to these therapies. **METHODS:** The FDA website was examined to identify breakthrough therapy medicines that had been approved up to 31 December 2014. The websites of the EMA (EU), Health Canada and TGA (Australia) were examined to determine their corresponding registration status. The NICE (England), IQWiG (Germany), TC (France), CADTH/pCODR (Canada) and PBAC (Australia) websites were examined to determine if and when the medicines had been considered for reimbursement/coverage. **RESULTS:** The FDA approved 14 breakthrough medicines as at 31 December 2014 for use in 16 unique patient populations (i.e. pairings). The mean time from submission to approval was 164 days. Twelve pairings are orphan drugs and 9 are for patients with cancer. As of 20 June 2015, 13 had been registered in the EU (mean time 326 days), 8 in Canada (275 days) and 9 in Australia (N/A). Four of the 15 pairings had been assessed by NICE (all recommended), 5 by IQWiG (4 additional benefit not quantifiable, 1 minor additional benefit), 6 by the TC (ASMR rating = II (2), III (1), IV (1), V (2)), 8 by CADTH/pCODR (6 recommended, 2 not recommended) and 7 by the PBAC (all recommended). **CONCLUSIONS:** Most of the 16 pairings were registered first in the US. The FDA evaluation period was shorter compared to other regulatory agencies. Some HTA agencies are yet to consider many pairings whilst others have dissimilar views on their additional clinical benefit.

PHP210

THE EVOLUTION OF HTA AS A COVERAGE DECISION-MAKING TOOL IN THE MIDDLE EAST AND NORTH AFRICA REGION

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OBJECTIVES: This research aims to characterize the extent to which health technology assessment (HTA) is currently being used to determine pharmaceutical coverage in the Middle East and North Africa (MENA) region. The objectives are to understand which decision-makers are currently undertaking this activity, the extent of its formalization, and in which parts of the healthcare system in each country there is greatest appetite for its implementation. **METHODS:** In-depth, qualitative interviews were conducted with a total of 11 payer decision-makers and 20 industry stakeholders in Egypt, Saudi Arabia, Turkey and the United Arab Emirates (UAE). Published literature and government websites were also reviewed. Primary and secondary research focused on current and evolving reimbursement decision-making procedures in these countries in addition to potential policy reforms. **RESULTS:** Of the countries considered, HTA focused on evaluation of specific pharmaceuticals appears to have gained the most traction in Saudi Arabia, where one of the public-sector payers has begun undertaking in-depth pharmacoeconomic (PE) analysis. In Egypt, while a PE unit has been established, its present role is to support the country's Drug Pricing Committee on a case-by-case basis. In Turkey, while PE data is required for reimbursement submission, budget impact is reported to remain the primary driver of national-level decision-making. Meanwhile, in the UAE, there is little evidence that the insurers increasingly responsible for coverage under the country's healthcare reforms are using formal HTA. **CONCLUSIONS:** The extent of HTA formalization and the specific areas of the healthcare system in which HTA operates vary across the MENA region, in line with the broader policy framework. Champions of further HTA development come from diverse stakeholder groups in each country. With time, it is expected that HTA will gain increasing traction across MENA, alongside arrangements such as risk-sharing schemes, with significant consequences for pharmaceutical access.

PHP211

ORPHAN DRUGS ASSESSMENT IN GERMANY: A COMPARISON WITH OTHER INTERNATIONAL HTA AGENCIES

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OBJECTIVES: Examine orphan drugs assessed by the German Federal Joint Committee (G-BA) between January 2011 and May 2015 and compare their assessments with those of other international HTA agencies. **METHODS:** GBA